PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/064349	20.03.2007	21.03.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/30 A61F2/38 A61F2/46

Applicant
CONFORMIS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Storer, John Telephone No. +49 89 2399-7247

Form (PCT/ISA/237) (Cover Sheet) (April 2005)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 105-108, 13-93

because:

☒ the said international application, or the said claims Nos. 105-108 relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 105-108, 13-93

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-12,24-55,94-104

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	10,11,30,42,49,50,53
	No:	Claims	1-9,12,24-29,31-41,43-48,51,52,54,55,94-104
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-12,24-55,94-104
Industrial applicability (IA)	Yes:	Claims	1-12,24-55,94-104
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III.

In accordance with Rule 67.1(iv) PCT, claims 105-108 are exempted from international preliminary examination, since they describe methods of medical treatment. In particular, the method involves the step of inserting the implant into a knee, which is part of a method of treatment of a human or animal body by surgery and is therefore exempted from examination (see the PCT International Search and Preliminary Examination Guidelines, Ch. 9.08).

Re Item IV.

This Authority considers that there are 6 inventions covered by the claims, which inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT. The separate inventions are as follows:

Claims 1-12, 94-104 define an implant interposed in a joint between a first articular surface and a second articular surface, the implant comprising:
a first surface for contacting the first articular surface such that motion of the implant is constrained; and
a second surface for contacting the second articular surface, the second surface allowing movement of the second articular surface.

Claims 13-23, 56-65 define an implant for insertion in a joint having a first articular surface, the implant comprising:
a first implant surface conforming to the first articular surface, the first articular surface including cartilage.

Claims 24-55 define an implant for insertion in a joint between a first articular surface and a second articular surface, the implant comprising:
a first implant surface for engaging the first articular surface, the first implant surface having one or more convexities and one or more concavities; and
a second implant surface for engaging the second articular surface, the second implant surface having at least one of a plurality of concavities and a plurality of convexities.

Claims 66-70 define an interpositional implant suitable for a knee joint, the implant comprising:

a superior surface arranged to oppose at least a portion of a femur; and
an inferior surface arranged to oppose at least a portion of a tibial surface, wherein the implant has a substantially U-shaped cross-section in at least one of a medial-lateral direction and an anterior-posterior direction.

Claims 71-76 define an interpositional implant suitable for a knee joint, the implant comprising:
a superior surface arranged to contact at least a portion of a femur;
an inferior surface arranged to contact at least a portion of a tibial surface, the superior surface and the inferior surface facing opposing directions and defining a thickness; and
a peripheral edge extending between the superior and inferior surfaces, the greatest thickness at the peripheral edge being at least 2 mm more than the smallest thickness of the implant.

Claims 77-93 define an implant for insertion in a joint between a first articular surface and a second articular surface, the implant comprising:
a first implant surface conforming to the first articular surface, the first articular surface including cartilage, the first implant surface having a periphery, the periphery including a stabilization mechanism for limiting motion of the implant in the joint; and
a second implant surface for contacting the second articular surface.

The common concept linking group of claims 1-12, 94-104 and group of claims 13-23, 56-65 is an implant for insertion in a joint having a first articular surface, the implant comprising a first implant surface for contacting the first articular surface. This concept, however, is well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the second group of claims is that the first implant surface conforms to the first articular surface. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant and the second group of claims addresses the problem of patient comfort. Therefore, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The common concept linking group of claims 1-12, 94-104 and group of claims 24-55 is an implant for insertion in a joint between a first articular surface and a second articular surface, the implant comprising a first implant surface for contacting the first articular surface and a second implant surface for contacting the second articular surface. This concept is again well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the third group of claims is that the first implant surface and the second implant surface have convexities and/or concavities. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant, as mentioned above, and the third group of claims addresses the problem of achieving a stable but mobile implant. Again, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The common concept linking group of claims 1-12, 94-104 and group of claims 66-70 is an interpositional implant comprising an inferior surface arranged to oppose at least a portion of a first articulating surface and a superior surface arranged to oppose at least a portion of a second articulating surface. This concept, however, is well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the fourth group of claims is that the implant has a substantially U-shaped cross-section in at least one of a medio-lateral direction and an anterior-posterior direction. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant and the fourth group of claims addresses the problem of improving the fit of the implant within the articulation. Again, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The common concept linking group of claims 1-12, 94-104 and group of claims 71-76 is again an interpositional implant comprising an inferior surface arranged to oppose at least a portion of a first articulating surface and a superior surface arranged to oppose

at least a portion of a second articulating surface. As mentioned above, this concept is well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the fifth group of claims is that the implant has a peripheral edge extending between the superior and inferior surfaces, the greatest thickness at the peripheral edge being at least 2 mm more than the smallest thickness of the implant. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant and the fifth group of claims addresses the problem of achieving an implant of appropriate thickness. Again, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The common concept linking group of claims 1-12, 94-104 and group of claims 77-93 is an implant for insertion in a joint between a first articular surface and a second articular surface, the implant comprising a first implant surface for contacting the first articular surface and a second implant surface for contacting the second articular surface. This concept, however, is well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the sixth group of claims is that the first implant surface has a periphery, the periphery including a stabilization mechanism for limiting motion of the implant in the joint. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant and the sixth group of claims addresses the problem of avoiding dislocation of the implant. Again, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

Re Item V

1. Reference is made to the following documents:
   D1: EP-A1-1 327 423 (CT PULSE ORTHOPEDICS LTD [CH] ZIMMER GMBH [CH]) 16 July 2003 (2003-07-16)
   D2: US 2004/133276 A1 (LANG PHILIPP [US] ET AL) 8 July 2004 (2004-07-08)
   D3: WO 2005/051239 A (CONFORMIS INC [US]; LANG PHILIPP [US]) 9 June 2005 (2005-06-09)
   D4: WO 03/061522 A2 (ADVANCED BIO SURFACES INC [US]; FELT JEFFREY C [US]; RYDELL MARK A [US) 31 July 2003 (2003-07-31)

Claims 1-12, 94-104

2. Although claims 1 and 94 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

3. The abovementioned lack of conciseness notwithstanding, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-9, 12, 94-104 is not new in the sense of Article 33(2) PCT.

   The document D1 discloses (the references in parentheses applying to this document) an interpositional implant (400) suitable for a knee joint, the implant comprising:
   a superior surface (408) arranged to oppose at least a portion of a femur;
   an inferior surface (404) arranged to oppose at least a portion of a tibial surface; and
   one or more protrusions (422) extending outwardly from the inferior surface, the protrusion (422) including a taper at the lowest surface of the protrusion in an anterior to posterior direction (see paragraphs 0020, 0021, 0032-0037 and figures 1, 2, 4 and 6-8).

   Thus, document D1 discloses all of the technical features of claim 1. In addition, the aforementioned disclosure of document D1 anticipates the subject-matter of

independent claim 94 and of dependent claims 4-9, 12 and 95-104.

The same result with respect to the lack of novelty of the subject-matter of claims 1, 4, 7-9, 12 and 94-104 is obtained with document D2 (see paragraph 0136 and figures 8K and 8L). In addition, the aforementioned disclosure of document D2 anticipates the subject-matter of dependent claims 2 and 3.

Therefore, the subject-matter of claims 1-9, 12 and 94-104 lacks novelty (Art. 33(2) PCT) and as such these claims do not meet the criteria of Article 33(1) PCT.

4. Claims 10 and 11 concern slight constructional changes in the interpositional implant of claim 1 which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claims 10 and 11 appears to lack an inventive step (Art. 33(3) PCT).

Claims 24-55

5. Although claims 24, 34 and 45 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

6. The abovementioned lack of conciseness notwithstanding, the subject-matter of claims 24-29, 31-41, 43-48, 51, 52, 54 and 55 does not meet the criteria of Article 33(1) PCT, because it is not new in the sense of Article 33(2) PCT.

Document D3 discloses an implant (e.g. as shown in Fig. 13A(3)) for insertion in a joint between a first articular surface and a second articular surface, the implant comprising:
a first implant surface (i.e. upper surface in Fig. 13A(3)) for engaging the first articular surface, the first implant surface having one or more convexities and one or more concavities; and
a second implant surface (i.e. lower surface in Fig. 13A(3)) for engaging the

second articular surface, the second implant surface having at least one of a plurality of concavities and a plurality of convexities (see paragraphs 0055-0061, 0077, 0078, 0095, 0096, claims 1 and 2 and figures 9, 10, 12D, 13(3)A-E).

Thus, document D3 discloses all of the technical features of independent claim 24. In addition, the aforementioned disclosure of document D3 anticipates the subject-matter of independent claims 34 and 45 and of dependent claims 25-29, 31-33, 35-41, 43, 44, 46-48, 51, 52, 54 and 55).

Therefore, the subject-matter of claims 24-29, 31-41, 43-48, 51, 52, 54 and 55 lacks novelty (Art. 33(2) PCT) and as such these claims do not meet the criteria of Article 33(1) PCT.

7. The features of claims 30, 42, 49, 50 and 53 have already been employed for the same purpose in a similar implant as disclosed in document D4 (see the abstract, page 27, lines 16-21, claims 1, 3, 4 and figure 1a). It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to an implant according to document D3, thereby arriving at an implant according to each of claims 30, 42, 49, 50 and 53.

   Therefore, the subject-matter of claims 30, 42, 49, 50 and 53 lacks an inventive step (Art. 33(3) PCT) and as such these claims also do not meet the criteria of Article 33(1) PCT.

8. The independent claims have not been delimited with respect to the closest prior art (documents D1/D2 or D3), which would have been appropriate (Rule 6.3(b) PCT).

9. Reference signs have not been used throughout the claims, which would have been appropriate (Rule 6.2(b) PCT).

10. The documents D1, D2 and D3 should have been identified in the description and

the background art disclosed therein briefly discussed (Rule 5.1(a)(ii) PCT).